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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

August 26, 1997

WARNING LETTER
SJN-97-24

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Curt M. Selquist
Company Group Chairman
Johnson & Johnson
One Johnson & Johnson Plaza WT703
New Brunswick, NJ 08933

Dear Mr. Selquist:

We are writing to you because on June 9, to July 17, 1997, an investigator from the Food & Drug Administration (FDA), San Juan District Office, during a plant inspection, collected information that revealed a serious regulatory problem involving the product known as Cidex* (Activated Dialdehyde Solution) which is manufactured at your facility, Arbrook Manufacturing Corp., Rd. #362 km. 0.5, San German, PR.

Under a United States Federal law, the Federal Food Drug and Cosmetic Act (Act), this product is considered to be a medical device because it is a liquid chemical germicide labeled for use as a sterilant and disinfectant for medical devices.

In legal terms, the product is adulterated under section 501 (h) of the Act because it was not manufactured in conformance with Good Manufacturing Practice Regulations for Medical Devices (GMP) as defined in 21 CFR 820. Specific significant GMP deviations reported during the inspection include:

> There appears to be a consistent problem in the blending process for the Activator Salts used to activate Cidex* Solution so that reblending or batch adjustments of the batches are frequently necessary in order for them to pass specifications. The reblending or batch adjustment steps are not included in the Device Master Record or Process Specification documents for this product, have never been validated and are not always reported on the processing records when performed. At least one lot of

Activator Salts, [redacted] was reblended 4 times, for three hours each time, before acceptable sample results were obtained.

In addition, there were some deficiencies found in the validation of the initial blending procedure for these salts because there was no testing of Sodium Bicarbonate content, even though failure of this test during production triggers a reblend. Samples to determine adequacy of mixing in the validation batches were not taken at all of the time points specified in the validation protocol.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Mary L. Mason, Compliance Officer, U.S. Food & Drug Administration, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of GMP's and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)- 638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA Good Manufacturing Practice Regulations affect your particular device or about the content of this letter, please feel free to contact Mary Mason at (787)-729-6894.

Sincerely yours,

Samuel Jones
District Director

cc: Mr. Francisco Rodriguez
Arbrook Manufacturing Corp.
P.O. Box 5005
San German, PR 00683